

REMARKS

Claims 52-56, 58-64, and 66-71 are pending. Claims 37-51, 57 and 65 have been canceled without prejudice or disclaimer. Claims 37-51 were canceled without prejudice or disclaimer as directed to a non-elected invention. Applicants reserve the right to pursue the canceled claims in a continuing application. Claims 52, 55, and 61-64 have been amended without prejudice or disclaimer. Claims 66-71 have been newly added. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, for example, see Specification, for example, at page 9, lines 3-13 and page 10, line 16 - page 12, line 21. No new matter enters by way of the foregoing amendment.

I. Objections to Specification

Applicants have amended the specification to update the status of U.S. Appl. No. 09/915,182 in accordance with the Office's suggestions. As such, Applicants respectfully request withdrawal of the objection.

The Office also objected to the disclosure for misspelling "*pulcherrima*." Office Action at page 2. Applicants have amended the specification in accordance with the Office's suggestions. As such, Applicants respectfully request withdrawal of the objection.

The Office has objected to the specification for allegedly incorporating essential material into the specification by reference to an unpublished U.S. application, foreign application or patent, or publication. Office Action at page 2. In objecting to the specification, the Office asserts that KAS I, KAS II, and KAS IV sequences from *C. pulcherrima* are improperly incorporated by reference to WO 98/46776. *Id.* Applicants respectfully disagree.

Applicants have not improperly incorporated material into the specification by reference to an unpublished U.S. application, foreign application or patent, or publication. As set forth in 35 C.F.R. § 1.57(c), "Essential material" is material that is necessary to:

(1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

(2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112; or

(3) Describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112.

The Office has provided no legal basis or evidence whatsoever that the disclosure incorrectly incorporated by reference an unpublished U.S. application, foreign application or patent, or publication. As described above in (1) - (3), incorporation by reference of "essential material" encompasses the invention as **claimed**. The Office appears to ignore this point when objecting to the specification. The Office seems to rest upon the misconception that an applicant is required to recite what is known in the art in addition to what the applicant is adding to the art. It does not. "Indeed, a patent need not teach, and preferably omits, what is well known in the art." *Falkner v. Inglis*, 448 F.3d 1357, 1365, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) (internal quotations and brackets omitted). Absent any evidence or legal basis to the contrary, Applicants respectfully submit that the Office has not met their burden.

For at least the above reasons, Applicants respectfully request that the Office withdraws this objection.

II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 52, 55-63, and 64¹ stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Office Action at page 3. In rejecting the claims, the Office asserts that "Applicant does not describe any isolated polynucleotides encoding KAS activity other than SEQ ID NO:1 from *Synechocystis* encoding a polypeptide of SEQ ID NO:2." Office Action at page 4.

Applicants respectfully disagree with the Examiner's rejections under 35 U.S.C. § 112, first paragraph. However, solely in order to facilitate prosecution, Applicants have amended claims 52, 55, and 61-64 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim rejections are rendered moot.

¹ Claims 55-63, and 64 depend from Claim 52.

Applicants thank the Examiner for the acknowledgment that “Applicant describes a polynucleotide of SEQ ID NO:1 from *Synechocystis* encoding a polypeptide of SEQ ID NO:2.” Office Action at page 3. Applicants also thank the Office for the acknowledgement that Applicants describe “polynucleotides from *C. pulcherrima* encoding KASI and KASII (WO 98/46776) having acyl chain specificities from 2:0-ACP to 14:0-ACP, and 8:0-ACP or medium chain length acyl chain substrates respectively; and the safflower delta-9 desaturase gene.” Office Action at page 4-5. Indeed, the Specification provides numerous β -ketoacyl-ACP synthase proteins and methods for using said proteins. In light of the disclosure, one of ordinary skill in the art would clearly recognize that the inventors were in possession of the presently claimed invention.

In light of these remarks, Applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

III. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 52, 55-63, and 64 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling one of skill in the art to make and/or use the invention. Office Action at pages 5-6. In support of this rejection, the Office asserts that “Applicant does not teach modified fatty acids in transformed plant seeds other than reduced saturated fatty acids in plants transformed with any other polynucleotide encoding a beta-ketoacyl-ACP synthase isolated from any other source other than the beta-ketoacyl-ACP synthase gene from *Synechocystis* of SEQ ID NO:1 encoding SEQ ID NO:2 and the genes from *C. pulcherrima* encoding KAS I and KAS IV in concert with the polynucleotide encoding the safflower delta 9 desaturase.” Office Action at page 6.

Applicants respectfully disagree with the Examiner’s rejections under 35 U.S.C. § 112, first paragraph. However, solely in order to facilitate prosecution, Applicants have amended claims 52, 55, and 61-64 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim rejections are rendered moot.

The Office has not met the evidentiary burden to impose an enablement rejection. A specification that discloses how to use a claimed invention “must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the

objective truth of the statements contained therein.” *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). The Office has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable the claimed invention.

It is submitted that Applicants have provided considerable direction and guidance, and have presented working examples such that it is well within the level of ordinary skill in the art to practice the invention without undue experimentation. The Office has not provided sufficient evidence to cast doubt on the guidance provided in the specification. Rather, the Office has provided generalizations regarding a lack of predictability in the art and the need for some experimentation.

Even assuming, *arguendo*, that the Office’s generalization regarding the unpredictable state of the art is accepted, the conclusion that undue experimentation would be required to practice the claimed method is inconsistent with the current state of the law. Specifically, the law provides that experimentation is not necessarily undue simply because it is complex, if the art typically engages in such experimentation. *See In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174, (Int’l Trade Comm’n 1983) *aff’d. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985).

Applicants thank the Examiner for the acknowledgment that the specification is enabling “for a method of decreasing the saturated fatty acid content in transgenic plant seeds transformed with SEQ ID NO:1 and a delta 9 desaturase from sunflower; or in the seeds of a transgenic plant transformed with KASI and KAS IV beta-ketoacyl-ACP synthase from *C. Pulcherrima* and a delta 9 desaturase from sunflower.” Office Action at page 5. Indeed, the Specification provides numerous β -ketoacyl-ACP synthase proteins and methods for using said proteins. Given this, Applicants respectfully submit that the claimed invention satisfies 35 U.S.C. § 112, first paragraph.

In rejecting claims 52, 55-64, the Office asserts that “Applicant does not teach modified fatty acids in transformed plant seeds other than reduced fatty aids in plants transformed with any other polynucleotide encoding a beta-ketoacyl-ACP synthase isolated from any other source

than the beta-ketoacyl-ACP synthase gene from *Synechocystis* of SEQ ID NO:1 encoding SEQ ID NO:2 and the genes from *C. pulcherrima* encoding KAS I and KAS IV in concert with the polynucleotide encoding the safflower delta 9 desaturase.” Office Action at page 6. Applicants disagree and submit that there is no requirement to provide all of the ways that the claimed invention can be practiced. MPEP § 2164.01(b). The enablement requirement is satisfied as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *Id.* This is exactly what Applicants have provided. By disclosing numerous examples of beta-ketoacyl-ACP synthase capable of modifying the saturated fatty acid content in transgenic plant seeds, Applicants have satisfied this requirement. Specification at page 28, line 1 - page 32, line 7; Examples 3-5; and Table 2.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

IV. Rejections under 35 U.S.C. § 102

Claim 52 stands rejected under 35 U.S.C. § 102 as allegedly being anticipated by Knauf *et al.* (U.S. patent 5,510,225). Office Action at page 8. In rejecting the claim, the Office asserts that “Knauf teaches the use of an isolated nucleotide encoding a beta-ketoacyl-ACP synthase II or isolated nucleotides encoding both a beta-ketoacyl-ACP synthase II and a delta 9 desaturase together in a vector or in separate vectors for the production of fatty acids having little or no completely saturated chains in the seeds of either corn, rapeseed, or soybean.” Office Action at page 7. The Examiner then goes on to assert that “[t]hus, the reference teaches all of the limitations of Claims 1, 7-8, 10-21, and 31-36.” Applicants respectfully disagree.

Applicants respectfully disagree with the Examiner’s rejections under 35 U.S.C. § 102. However, solely in order to facilitate prosecution, Applicants have amended claim 52 without prejudice or disclaimer. As such, Applicants respectfully assert that the claim rejections are rendered moot.

At the outset, Applicants note that claims 1, 7-8, 10-21, and 31-36 have been previously canceled and are not currently pending. As such, the rejections over claims 1, 7-8, 10-21, and 31-36 are not applicable.

Moreover, Knauf *et al.* does not disclose or fairly suggest a heterologous β -ketoacyl-ACP synthase comprising a coding sequence at least 95% identical to SEQ ID NO: 1. Additionally, Knauf *et al.* does not disclose or fairly suggest a heterologous β -ketoacyl-ACP synthase comprising an amino acid sequence at least 95% identical to SEQ ID NO: 2. Knauf *et al.* does not even disclose SEQ ID NO:1. The Office acknowledges this by noting that "Knauf does not teach SEQ ID NO:1 encoding SEQ ID NO:2." Office Action at page 9. As such, Knauf *et al.* can not anticipate the claimed invention.

For at least the above reasons, Applicants respectfully request that the Office withdraws this rejection.

V. Rejections under 35 U.S.C. § 103

Claims 52-64 stand rejected under 35 U.S.C. § 103(a) over Knauf *et al.* (U.S. patent 5,510,225) in view of Kaneko *et al.* (DNA Research, Vol. 3, pp. 109-136, June 19, 1996), and further in view of Applicants' Specification. Office Action at page 9. Applicants respectfully disagree and traverse for at least the reasons that follow.

At the outset, Knauf *et al.* does not disclose, or suggest, all of the elements of the invention as currently claimed. Even if Knauf *et al.* could be combined with Kaneko *et al.*, Kaneko *et al.* does not remedy this deficiency and in no way suggests the claimed invention. As described above, the Examiner acknowledges that Knauf *et al.* is by itself deficient to reject the claimed invention and that "Knauf does not teach SEQ ID NO:1 encoding SEQ ID NO:2." Office Action at page 9. Kaneko *et al.* does not remedy this deficiency and in no way suggests the claimed invention.

Whatever else Kaneko *et al.* describes, Kaneko T. *et al.* does not describe an isolated polynucleotide comprising the nucleotide sequence comprising SEQ ID NO: 1. The Office has offered no evidence that Kaneko *et al.* expressly describes SEQ ID NO: 1. Moreover, Applicants strongly disagree with the Office's assertion that the protein described by Kaneko *et al.* "inherently teaches" the polynucleotide sequence of SEQ ID NO: 1. Office Action at page 9.

The Office is reminded that, in the context of obviousness, “[a] prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein.” *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995). By analogy, because a reference that discloses a protein sequence will teach an enormous number of potential DNA sequences, that reference cannot by itself inherently specify the one correct DNA sequence while excluding the enormous number of other potential DNA sequences that could code for the same protein. *See, e.g., In re Meyer*, 599 F.2d 1026, 1031 (C.C.P.A. 1979).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully assert that the Office has failed to establish a *prima facie* case of obviousness because the Office has not provided an adequate explanation of the suggestion or motivation to combine the teachings of Kaneko *et al* and Knauf *et al*. The Office alleges that one of ordinary skill in the art would have been motivated to substitute the beta-ketoacyl-ACP synthase II gene discussed by Knauf *et al*. with the beta-ketoacyl-ACP synthase II gene discussed by Kaneko *et al*. Office Action at page 10. Applicant respectfully disagrees. Whatever else Knauf *et al*. describes, Knauf *et al*. provides no suggestion or motivation to use a KASII gene from the cyanobacterium *Synechocystis*, in place of a plant KAS II gene. In fact, Knauf *et al*. teaches away from the suggested combination of references, because Knauf *et al*. only discusses the isolation and use of KASII and delta-9 desaturase genes from plants such as *S. oleracea* (column 18, line 42), *C. tinctorius* (column 50, lines 27-30), *Brassica campestris* (column 3, lines 59-60), and *Ricinus communis* (column 26 line 43). Applicants therefore

respectfully disagree with the Office's assertion that one of skill in the art would have been motivated to combine the teachings of Kaneko *et al.* and Knauf *et al.*

Moreover, the Office has provided no motivation or suggestion to use KAS I and KAS IV sequences instead of the KAS II protein asserted by the Office to be disclosed in Knauf *et al.* Rather, the Office generally asserts that it would be "obvious given the lack of criticality." Office Action at page 10. This is not enough. Additionally, the Office impermissibly uses Applicants' own specification as motivation by asserting that "Applicant's specification teaches that KAS I and IV sequences from *C pulcherrima* and the sunflower delta 9 desaturase were known in the art." Office Action at page 10. Irrespective of this hindsight-based assertion, the Office fails to provide any evidence whatsoever of why one of ordinary skill in the art at the time the invention was made would be motivated to use KAS I and KAS IV sequences from *C. pulcherrima* instead of KAS II.

The Office has failed to establish a *prima facie* case of obviousness because there would have been no reasonable expectation of success, at the time the invention was made, in combining the teachings of Kaneko *et al.* and Knauf *et al.* Applicant respectfully points out that, as described above, Knauf *et al.* teaches the isolation and use of KASII and delta-9 desaturase genes from plants. One of skill in the art would therefore have no reasonable expectation of success that a cyanobacterial KASII gene would function sufficiently well in plants to produce altered fatty acid levels.

Finally, the Office has failed to establish a *prima facie* case of obviousness because the combined teachings of Kaneko *et al.* and Knauf *et al.* do not teach or suggest all the claim limitations. As described above, whatever else Kaneko *et al.* and Knauf *et al.* describe, neither reference describes an isolated polynucleotide comprising the nucleotide sequence comprising SEQ ID NO: 1 or a KAS I and IV sequences from *C pulcherrima*. For the foregoing reasons, Applicant therefore respectfully asserts that the Office has failed to establish a *prima facie* case of obviousness for Knauf *et al.* in view of Kaneko *et al.*

In light of these remarks, Applicant respectfully requests withdrawal of this rejection of claims 52-64 under 35 U.S.C. § 103 for purportedly being unpatentable over Knauf *et al.* in view of Kaneko *et al.*

CONCLUSION

Each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Kristan Lansbery".

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